

NOV 19 2013

K131377 (1/2)

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	May 13, 2013
Trade Name:	HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant
Common Name:	MTP hemi-toe prosthesis
Device:	Prosthesis, Toe, Hemi-, Phalangeal
Regulation Number:	21 CFR 888.3730
Regulation Name:	Toe joint phalangeal (hemi-toe) polymer prosthesis
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	KWD

Device Intended Use

Hemi-Arthroplasty Implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement or without bone cement.

Device Description

The HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant incorporates an articular resurfacing component and a cancellous taper post component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Resurfacing Component: Cobalt-Chromium Alloy (Co-Cr-Mo)

Surface Coating: Titanium (CP Ti)

Taper Post Component: Titanium Alloy (Ti-6Al-4V)

The HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant is a single use implant with updated indications for use with or without bone cement to be consistent with predicates, and updated general terminology for MTP. The implant is otherwise identical to the sponsor's previously cleared and commercially marketed implant.

Referencing predicate devices, similar indications have been cleared since 2007. Such history of use demonstrates the differences in indications are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, nor do they affect the safety and effectiveness of the device when used as labeled.

Substantial Equivalency:

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

- | | |
|---|---------|
| • CAP™ Great Toe Resurfacing Hemi-Arthroplasty Implant | K031859 |
| • Solana Surgical LLC, Metatarsal Decompression Implant | K113752 |
| • Vilex Cannulated Metallic Hemi Implant | K102401 |

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices:

- Intended for the metatarsophalangeal joint
- Similar indications for use
- Similar device designs
- Same Cobalt and Titanium implant materials
- Implants available anatomically curved
- Similar fixation options

Clinical data was provided in support of the substantial equivalency. Data was obtained from over 100 patients with follow-up ranging out to 5 years. Results demonstrated the safety and effectiveness of the HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant is adequately supported by the substantial equivalence information provided within this Premarket Notification.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Arthrosurface, Incorporated
Ms. Dawn J. Wilson
Vice President of Quality and Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K131377

Trade/Device Name: HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: November 5, 2013
Received: November 6, 2013

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K131377

Device Name: HemiCAP® MTP Resurfacing Hemi-Arthroplasty Implant

Indications for Use:

Hemi-Arthroplasty Implant for the metatarsophalangeal joint for use in the treatment of patients with degenerative and post-traumatic arthritis in the metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is a single use implant intended to be used with bone cement or without bone cement.

Prescription Use X Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

